Response/Election #9

10/15/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 24741-1523

In re patent application of:
GRUNERT *et al.*

Application No.: 09/807,509 Group Art Unit: 1642

Filed: June 25, 2001 Examiner: Helms, Larry Ronald

For: PROCESS FOR PREPARING ANTIBODIES AGAINST A POLYPEPTIDE IN WHICH THE NUCLEIC ACID ENCODING THE PEPTIDE IS KNOWN

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

Sir:

This responds to the Office Action of September 18, 2002, a response to which is due October 18, 2002. Applicants do not believe that a Petition for Extension of Time or fees are required. In the event this is not correct, applicants request such extension of time and authorize the Commissioner to charge the undersigned's account No. 08-1641.

Applicants respectfully traverse the restriction requirement in the Office Action of September 18, 2002. The Examiner's lack of unity of invention determination is based upon an application of the combined teachings of Ulivieri, *et al. J. of Biotech.* 51: 191-194 (1996) and WO 97/07132, which according to the Examiner, render the invention of claim 1 obvious. Because the Examiner believes this invention is obvious, he subjects the invention to what appears to be an election of species requirement in which each group of claims is limited to a specific detection signal, each of which is said to be non-obvious over the others and non-obvious over the prior art.

Applicants traverse this rejection because they believe such rejection to be based upon a misreading of claim 1. Specifically, Ulivieri teaches the basic mechanism of DNA immunization to create hybridomas in mouse splenocytes. The splenocytes produce monoclonal antibodies. The hybridoma supernatants are screened for the presence of antibodies using a recombinant protein. The present invention, on the other hand, does not require one to isolate the recombinant protein. The claimed *in vitro* test system allows the practitioner to deliver a DNA vector into mammalian cells, in culture which express the protein on the cell surface, thereby providing an optimal assay

system for detecting antibodies. The combined teachings of the cited reference do not suggest this assay.

The Examiner's election of species requirement further characterizes the claimed invention as DNA vectors carrying various stages. This is not correct. Applicants claim a combination of steps in a system to both immunize and assay for an antibody. The combination of different tags enables one to develop an immune response and simultaneously test for the presence of antibodies in sera of immunized animals or in the hybridoma supernatants in an in vitro test. The same constructs are used for both purposes. The cited art does not suggest such a system.

In view of the above explanations, applicants submit that the election of species requirement in this application is not proper and respectfully request the Examiner to reconsider and withdraw it. However, if applicants are forced to make an election, applicants elect Group IV using the GPI residue as a detection signal.

Applicants reserve the right to pursue non-elected subject matter in one or more divisional application.

Examination on the merits is awaited.

Respectfully submitted,

Date: October 10, 2002

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